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TITLE OF THE INVENTION *(500 characters max.)*

SYSTEM AND METHOD FOR SELF-MEASUREMENT OF INTRAOCULAR PRESSURE

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Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service via Express Mail Label No. EV 185 602 868 US in an envelope addressed to: Box Provisional Patent Application, Commissioner for Patents, United States Patent and Trademark Office, Washington, D.C. 20231

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(Signature)

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PROVISIONAL APPLICATION FILING ONLY

SYSTEM AND METHOD FOR SELF-MEASUREMENT OF INTRAOCULAR PRESSURE

BACKGROUND OF THE INVENTION

Intraocular pressure (IOP) is a physiological parameter routinely measured by eye care professionals. Elevated IOP is the most important risk factor in primary open angle glaucoma (POAG) which, combined with normal tension glaucoma (NTG), is the second leading cause of irreversible blindness in the United States. Patients with POAG and NTG have the same characteristic optic neuropathy (cupping) and visual field loss, but in NTG the IOPs have never been found to be elevated. Elevated IOP is also found in patients with ocular hypertension (OHT), but not the neuropathy or field changes. The only current treatment for POAG, NTG and OHT is reduction of IOP. The instrument that is the reference standard for IOP measurement is the Goldmann applanation tonometer, used worldwide by ophthalmologists for over 40 years.

Glaucoma management, which is so dependent on IOP, would benefit greatly by the acquisition of more IOP data. Essentially all IOP measurements are obtained on visits to the ophthalmologist's office – usually one measurement during typical office hours, and rarely more than one visit every two or three months. In glaucoma management, there is no parallel to the ubiquitous monitoring by diabetic patients of capillary blood glucose or by arterial hypertensive patients of blood pressure and heart rate. For these conditions, adjuncts in patient care increase the volume of measurements during clinic hours as well as extend the monitoring beyond the eight hours that the clinic is open.

Measurement of IOP at different times of the day usually yields different readings, sometimes highest at night. However, there is considerable variability in the diurnal pattern between individuals. Differences in IOP throughout the day are of special interest. In some POAG patients, despite treatment which results in normal IOPs (measured in the ophthalmologist's office), cupping and field

loss can progress. In NTG, cupping occurs and can progress in the presence of IOP within the normal statistical limits (measured in the ophthalmologist's office). In OHT, over time, cupping and field loss can develop. The question in these cases is whether the progression (in POAG and NTG) and development (in OHT) of glaucoma damage is due to elevated IOP at times of the day when they cannot be measured in the ophthalmologist's office.

The answer is a clinical test with a long history – the diurnal IOP curve – which involves measuring a patient's IOP a number of times throughout a 24 hour period. In **"Emerging Perspectives in Glaucoma: Optimizing 24-hour Control of Intraocular Pressure"** (*Am J Ophthalmol* 2002, 133: S1-S10), Wax et al. summarize the importance of 24-hour control of IOP in the management of POAG and NTG to prevent patients from progressing to blindness (*see also* Oliver et al., *Am J Ophthalmol* 2002, 133: 764-772). Perhaps in OHT, in which standard medication protocols reduce the incidence of progression to cupping and visual field loss, an additional risk predictive factor might be uncovered in this inhomogeneous group by expanding the scope of IOP testing from an 8- to a 24-hour day.

However, the diurnal IOP curve is a problematic test because it typically involves admitting the patient to a hospital or sleep laboratory where a resident or technician measures IOP at intervals throughout the day and night. It seems likely that results of diurnal curves might be affected by the inherently more stressful institutional setting, sleeping in an unfamiliar bed in a strange hospital room or sleep laboratory, and being awakened multiple times during the night by someone who measures the patient's IOP. In one systematic study of diurnal IOP using the Goldmann tonometer (Hayreh et al., *Am J Ophthalmol* 1994, 117: 603-624), the earliest measurement was at 7 am and the latest was at 10 pm. Another study reported Goldmann readings throughout the night, sitting and "10 meters" from the patient's room (Ido et al., *Ophthalmol* 1991, 98: 296-300). This study showed that frequent awakening of the patient in a hospital for the measurement can be a confounding factor, and so the research design was altered to awaken the patient once at night at a random time. Therefore, obtaining a full diurnal curve with this protocol would require the patient to be admitted to the hospital or a sleep

laboratory four to five different nights, ideally with a slit lamp with a Goldmann tonometer in the patient's room to measure IOP immediately upon awakening while in the lying position. Of course, this is not possible economically and logistically for in-patient care or screening. In reality, diurnal IOP curves are currently not generally part of the standard of care in glaucoma management, except in clinical research centers. When diurnal curves are obtained, data are typically limited to several points during a single, likely uncomfortable, night.

In obtaining diurnal IOP curves, the tonometric method is an important, but not a simple, consideration. Because of the complicated logistics, this test has often been done without using the Goldmann applanation tonometer. For example, recently, Liu et al. reported that the lying position is a factor in the increase in IOP in some patients, although the nighttime values in the lying position were not compared with sitting nighttime IOP measurements (*Invest Ophthalmol Vis Sci* 1999, 40: 2912-2917). This extensive study was based on measurements made with a pneumotonometer, which has been shown to correlate well with the Goldmann applanation tonometer (*see* Quigley and Langham, *Am J Ophthalmol* 1975, 80: 266-273). However, the pneumotonometer is an instrument on which ophthalmologists do not base their clinical decisions.

The effect of a subject's body position on IOP has been the source of much debate in the literature. Of the many daytime studies, most using the Goldmann tonometer, most have shown a 1-4 mm Hg higher pressure in the lying position (Tsukahara and Sasaki, *Br J Ophthalmol* 1984, 68: 389-392; Yamabayashi et al., *Br J Ophthalmol* 1991, 75: 652-655; Anderson and Grant, *Invest Ophthalmol* 1973, 12: 204-212), some a larger difference (Leonard et al., *Br J Ophthalmol* 1983, 67: 362-366), and some no difference at all (Frampton et al., *Am J Optom Physiol Opt* 1987, 64: 54-61; Strobl and Follman, *Ophthalmologica* 1962, 144: 57-61; Kindler-Loosli et al., *Albrecht v. Graefes Arch klin exp Ophthalmol* 1975, 194: 17-21). There has been no study of nighttime Goldmann IOP in patients in the lying position. In addition to position, other factors have been reported to influence a patient's IOP throughout the night, including the light that a patient's eyes receive (Frampton et al.), the blood melatonin level (Willdosoet et al., *Ophthal Physiol Opt*

1993, 13: 357-365), a blood pressure change associated with waking (Zeimer et al., *Ophthalmol* 1990, 97: 547-550), the fact that the patient has or has not slept (Frampton et al.; Brown et al., *Ophthal Physiol Opt* 1988, 8: 246-248; Brown et al., *Ophthal Physiol Opt* 1988, 8: 249-252), and the actual state of sleep the subject was in when awakened (Noel et al., *Ophthalmol* 2001, 108: 139-144). This body of research makes it seem unlikely that a higher IOP at night, when it occurs, is due entirely to position.

The disadvantages for both patients and medical personnel of an institutional site in measuring diurnal IOP led to the idea of home tonometry, which Posner noted in 1965, having patients use a Maklakoff type tonometer (*Eye & Ear Nose Throat Mon* 1965, 44: 64-66). Jensen and Maumenee (*Am J Ophthalmol* 1976, 76: 929-932) and later Alpar (*Glaucoma* 1983, 5: 130-132) had a family member measure the patient's IOP with the Schiotz tonometer.

A more recent approach to measuring diurnal IOP in the home environment introduced the concept of self-tonometry. Two instruments, both hand-held and based on the applanation principle of the Goldmann tonometer, have been studied – one by Zeimer and Wilenski (*IEEE Trans Biomed Eng* 1982, 29: 178-183) in which the IOP endpoint is detected by a photodiode array optical device instead of the signature pattern recognition used in Goldmann tonometry. The other was developed by Groenhoff et al. using a microprocessor controlled optical sensor (*Int Ophthalmol* 1992, 16: 299-303). Both showed promise in the hands of their inventors, but others have found the correlation of patient measurements and ophthalmologist measurements using the Goldmann tonometer problematic, and also found that these devices can be moderately difficult to use. What may be most significant is the limited interest in these instruments since their invention in the 1980's, despite the concurrent heightened awareness of the potential importance of diurnal IOP.

As would be expected, self-tonometry with non-contact tonometers (*see* Stewart et al., *Ann Ophthalmol* 1991, 23: 177-182; Carenini et al., *Int Ophthalmol* 1992, 16: 295-297) that have been shown to be less reliable than the

Goldmann method in the hands of ophthalmologists has met with a general lack of professional interest. Finally, the Tono-Pen®, based on the McKay-Marg applanation principle is used by some ophthalmologists' technicians for IOP screening. While it has occasionally been used for self-tonometry (*see* Kupin et al., *Am J Ophthalmol* 1993, 116: 643-644), it is not easy to apply to oneself, and an ophthalmologist would not depend on measurements with a screening instrument as a basis for clinical decisions.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an end elevational view of the self-tonometry apparatus according to the present invention;

FIGURE 2 is a perspective view of the self-tonometry apparatus of FIG. 1;

FIGURE 3 is a schematic illustration of the correct applanation pattern for self-measurement of IOP;

FIGURE 4 is an actual video frame of the correct pattern for self-measurement of IOP as seen by the patient;

FIGURE 5 is an actual video frame of the pattern seen by the patient once the tonometer tip is aligned to the eye;

FIGURE 6 is a schematic illustration if no pattern is observed;

FIGURE 7 is a schematic illustration of the pattern observed if the apparatus is too close to the patient's face;

FIGURE 8 is a schematic illustration of the pattern observed when the fluorescein ring is too wide;

FIGURE 9 is a schematic illustration of the pattern observed when the fluorescein ring is too narrow;

FIGURE 10 is a schematic illustration of the pattern observed when the tonometer tip is too far to the left on the eye;

FIGURE 11 is a schematic illustration of the pattern observed when the tonometer tip is too far to the right on the eye;

FIGURE 12 is a schematic illustration of the pattern observed when the tonometer tip is too high on the eye;

FIGURE 13 is a schematic illustration of the pattern observed when the tonometer tip is too low on the eye;

FIGURE 14 is a schematic illustration of the pattern observed when the pressure is too low;

FIGURE 15 is a schematic illustration of the pattern observed when the pressure is too high;

FIGURE 16 is a graph of diurnal IOP measurements for a patient taken during a three month period;

FIGURE 17 are graphs of 24-hour home IOP self-measurements in four patients;

FIGURE 18 is a schematic illustration of a first embodiment of a hand-held self-tonometry apparatus according to the present invention;

FIGURE 19 is a schematic illustration of a second embodiment of a hand-held self-tonometry apparatus according to the present invention; and

FIGURE 20 is a schematic illustration of an applanation mechanism for the embodiments of FIGS. 18 and 19.

DESCRIPTION OF THE INVENTION

The present invention is directed to a system and method for patient self-measurement of intraocular pressure (IOP). The present invention provides a diagnostic tool that will enable ophthalmologists to obtain a vastly increased volume of patient IOP information throughout 24 hours. This could greatly improve medical control of IOP, the primary risk factor of glaucoma. The present invention also demonstrates the value of self-tonometry for studying the circadian rhythm of IOP. This could lead to the elucidation of the role of higher IOPs than have been measured clinically as a likely important factor in progression of the optic neuropathy of POAG and NTG, and in development of the neuropathy in patients with OHT.

Referring first to FIGS. 1 and 2, a self-tonometry apparatus according to the present invention is illustrated. The self-tonometry apparatus includes a joystick mechanism and a chin-forehead rest, similar to a conventional slit lamp (Haag-Streit). However, according to the present invention, the microscope and illumination tower of the slit lamp are replaced by illumination and imaging components. A support with an arm extends from the joystick base to the proper level for a tonometer guide plate, wherein the support includes three brackets for mounting the illumination and imaging components.

One bracket, attached to the Galilean power changer of the microscope, includes pockets each sized to hold a LCD color video monitor (for example, a 2.5" screen, Casio EV-570, Casio, Denver, CO; or a 2.9" screen, 4.7 oz., 80 x 91 x 27 mm, Citizen M329 Mark II, CBM America Corporation, Torrance, CA). A color video monitor (preferably 13" CRT) can also be used to compare its applanation pattern image with that of the LCD. A second bracket attaches an ultra-miniature color video camera (for example, Canon PowerShot S40, Canon, Lake Success, NY; 1.3 oz, 25 x 25 mm, Defender Security; or 3.6 mm lens;

Sony ¼" CCD; horizontal resolution more than 380 TV lines) to one microscope ocular, wherein its video output is fed to the monitors. The other ocular may be used by an ophthalmologist to obtain the "experienced measurer" values described below. The third bracket attaches a pair of loose lens holders (for example, Humphrey-Zeiss, Dublin, CA) to the apparatus for corrective lenses and additional plus for the 6 inch eye-to-screen distance.

The wiring for each component preferably runs to a single cable connector and then to a power supply. A standard Goldmann applanation tonometer (16.9 oz) is attached to the tonometer guide plate for self-tonometry, but otherwise need not be dedicated to the self-tonometry apparatus. As shown in FIG. 1, a blue LED illuminator is placed close to and at approximately a 60° angle to the Goldmann tonometer tip.

The self-tonometry apparatus of the present invention is preferably designed for portability in that it is light, compact and easy to use in a patient's home environment. Lightweight materials, such as aluminum and plastics, can be used to construct the joystick mechanism and the chin/forehead rest. Compactness can be achieved with telescoping vertical supports of the chin/forehead rest. Also, the wiring is preferably minimized and the transformers simplified for home use.

The self-tonometry method according to the present invention is as follows. The surface of one eye of each patient is first anesthetized with a drop of fluorescein and benoxinate (for example, Fluorox, Ocusoft, Inc.), after which the patient takes position in contact with the chin-forehead rest. With the patient's chin and forehead in position, she/he moves the joystick with one hand to bring the tonometer tip close to one eye, aligning the tip by looking directly at it. Using the joystick, the patient then brings the tonometer tip into contact with his/her cornea. As the tonometer tip applanates (flattens) the cornea of one eye, the patient views the applanation pattern (typically green in color) on the video monitor with the other eye. Next, the patient uses the joystick to adjust the tonometer tip position to center the applanation pattern on the monitor. Finally, with the other hand, the patient

turns the tonometer dial to obtain the applanation endpoint pattern for IOP measurement. The patient will then repeat the procedure on the other eye.

FIG. 3 is a schematic illustration of the correct applanation endpoint pattern for self-measurement of IOP. The half circles are centered and are the same size, and the inner edges of the half circles just meet. To position the pattern, the patient can move the joystick away from himself, towards himself, to the left, and to the right. The patient can also turn the joystick in a clockwise manner and in a counterclockwise manner to move up and down. FIG. 4 shows an actual video frame of the correct pattern for self-measurement of IOP as seen by the patient.

If the patient has aligned the tonometer tip to his/her eye, the patient should see a pattern as shown in the video frame of FIG. 5. If there is no pattern, the screen will appear as in FIG. 6. The patient should check to see that his/her head is placed firmly against the headrest, and that the tonometer tip is in contact with his/her eye. After adjustment, the pattern should appear like that of FIG. 3. If the pattern in FIG. 7 appears and does not change upon adjustment of the tonometer dial, the apparatus is too close to the patient's face. The patient should withdraw his/her head from the apparatus and start the measurement over.

In the pattern illustrated in FIG. 8, the fluorescein ring is too wide. To correct this problem, the patient should remove the tonometer from his/her eye and lightly dab the tonometer tip with a cotton swab. In the pattern shown in FIG. 9, the fluorescein ring is too narrow. Blinking the eyes a few times to spread the dye will correct this problem.

In the pattern depicted in FIG. 10, the tonometer tip is too far to the left on the eye. The patient should move the joystick to the right to bring the entire image into view. In the pattern of FIG. 11, the tonometer tip is too far to the right on the eye. The patient should move the joystick to the left to bring the pattern fully into view. If the patient sees the pattern shown in FIG. 12, the tonometer tip is too high on the eye. The patient should turn the joystick in a clockwise direction to move the image down into view. If the patient sees the pattern of FIG. 13, the

tonometer tip is too low on the eye. The patient should turn the joystick in a counterclockwise direction to move the image up into view.

If the rings are not touching, as illustrated in FIG. 14, the pressure is too low. The patient should turn the tonometer dial towards himself to increase the pressure. After the pressure is increased, the pattern should look like that of FIG. 3. If the rings are overlapping, as in FIG. 15, the pressure is too high. The patient should turn the tonometer dial away from himself to decrease the pressure. After the pressure is decreased, the pattern should look like that of FIG. 3. Of course, the directional movement of the joystick and tonometer dial described above is only exemplary.

To ensure that a patient understands and is comfortable and confident in his/her operation of the self-tonometry apparatus of the present invention, an initial training session is preferably held with each patient. This training session preferably includes the use of an instructional video that will guide the patient through the basic manipulation of the apparatus for the range of applanation patterns they could see on the video monitor screen. The patient is also preferably given a pamphlet with pictures of the patterns and instructions on how to obtain the correct endpoint. The training session can also include patient hands-on practice in obtaining the proper applanation pattern using a model eye (for example, Model TE-210, EyeTech, Morton Grove, IL), that will mount to the chin-forehead rest of the apparatus. This will serve as a simulator so that the patient can become familiar with manipulation of the joystick and tonometer dial to obtain the correct applanation pattern before measuring her/his IOP. Because the model eye can be set to particular pressures, it can also allow the technician/trainer to gauge the patient's facility with the apparatus.

In a preferred embodiment, the protocol for learning and testing is as follows. During five days, the patient will visit the clinic at specified times during the day, for example at 9:00 am, 12:00 pm, 3:00 pm, 6:00 pm and 9:00 pm. During each visit, the patient will take measurements of their IOP using the self-tonometry apparatus of the present invention. The patient will apply 1-2 drops of

fluorescein and benoxinate (for example, Fluorox, Ocusoft, Inc.) to the surface of their eyes for anesthetic. Taking into account inter-observer variability and intra-observer measurement bias, applanation measurements should follow the protocol of AGIS (*see* Gordon et al., *Arch Ophthalmol* 1999, 117: 573-583; Anderson and Grant, *Invest Ophthalmol* 1973, 12: 204-212) and OHTS (*see* Gaasterland et al., *Am J Ophthalmol* 2000, 130: 429-440; Leonard et al., *Br J Ophthalmol*, 1983, 67: 362-366). Two consecutive self-measurements are taken, and if the measurements differ by 2 mm Hg or more, then a third measurement is taken. An experienced measurer, such as an ophthalmologist, then makes two consecutive measurements using a standard slit lamp setup, again taking a third measurement if the first two differ by 2 mm Hg or more. This cycle is repeated five times for each eye. An objective observer records all the values so that both the experienced measurer and the patient are masked to all the results (Gillow and Aggarwal, *Br J Ophthalmol* 1995, 79: 1057-1058).

The table below summarizes the experiments in six patients in which each measured her/his IOP and then had measurements made by an experienced measurer as described above. Patients # 1, 2, 3 and 4 were introduced to self-tonometry, but not trained, and their data were then acquired on another day. Patients # 5 and 6 were tested immediately after a very brief introduction and no trial measurements. All measurements were made in a paired design (5 measurements per patient, pairing the patient's measurements with the experienced measurer's measurements), and measurements were made on the right eye only. For all patients except #6, the mean difference between self- and experienced-measurements was within 1.25 mm Hg. Further, the average standard deviation of differences (patient minus experienced measurer) was £ 1.06. These data indicate that patients can learn to effectively and accurately practice self-measurement of IOP using the self-tonometry apparatus of the present invention.

Patient #	Age	Mean IOP Difference	Standard Deviation of Difference
1	50	-0.45	1.54
2	71	0.20	0.74
3	53	-0.35	1.38
4	78	-1.25	0.47
5	75	0.90	1.33
6	22	-2.10	0.91
MEANS =		-0.51	1.06

The measurements by an experienced measurer for each hour can be averaged to form a daytime IOP template for assessing the reliability of self-tonometry data acquired at home. FIG. 16 illustrates the daytime IOP data obtained in one patient by an experienced measurer. This experiment, conducted in an 83-year female with ocular hypertension, demonstrates the range of IOP values and the circadian pattern of this physiologic parameter, largely during typical clinic hours. Her IOPs had long been remarkably consistent, showing a quite predictable circadian pattern – higher in the morning and lower in the afternoon, and higher in her right eye than in left her eye. She has normal optic discs and normal visual fields, both of which were monitored during the course of this experiment. Before the experiment began, she was told to discontinue the bedtime drop of latanoprost, which had controlled her IOPs, and then, after a two week washout period, the series of IOPs were obtained over three months.

The table below is a summary of these hour-to-hour IOP data which is useful in assessing natural (physiologic) day-to-day and diurnal changes in IOP that could be anticipated for patients, i.e., intra-patient natural variation. These IOP data show variation during the day, from eye-to-eye, and, of special significance, from day to day at a given hour, as seen in the ranges.

Time	Right Eye		Left Eye		Number of
	Median	Range	Median	Range	Observations
9-9:59 am	22.5	17.0 - 27.5	22.5	15.5 - 26.5	13
10-10:59 am	23.0	17.5 - 25.0	21.5	19.0 - 26.0	28
11-11:59 am	21.75	19.5 - 23.0	19.75	18.5 - 22.0	6
12-12:59 pm	19.75	18.0 - 21.5	19.25	18.0 - 20.5	2
1-1:59 pm	23.5	--	20.5	--	1
2-2:59 pm	18.5	18.0 - 20.0	17.0	16.5 - 18.0	5
3-3:59 pm	19.5	17.5 - 20.5	18.25	15.5 - 20.5	14
4-4:59 pm	19.25	15.0 - 22.5	17.25	14.5 - 22.5	16
5-5:59 pm	18.0	16.5 - 20.5	17.25	15.0 - 22.0	6

Two, three, four, and five IOP measurements for an eye were randomly sampled at various hours throughout the day and then tolerance limits were computed based on the means and standard deviations derived from this data. These tolerance intervals presented the minimum and maximum values that would cover the central 75% of the population of all possible measurements for this patient at that hour with 90% confidence. The results demonstrated variation dependent on the number of measurements collected for the patient at various times during the day. This patient's physiologic range of IOP for an hour of the day can be confidently determined by four measurements.

A study of use of the self-tonometry apparatus by glaucoma-age patients in their familiar home setting and during normal daily life can also be conducted. In addition to self-tonometry at the specified times for comparison to the daytime templates, the patients preferably perform self-tonometry for at least one time point during the night (for example, 12:00 am, 3:00 am, or 6:00 am). The nocturnal time points are distributed throughout the week to minimize disruption to their sleep habits. A social worker/occupational therapist/student nurse familiar with self-tonometry will visit each patient's home to assure proper set-up of the self-

tonometry apparatus of the present invention and to check that the patient's ability to use the apparatus in a clinic setting is transferred to the home environment.

The self-tonometry apparatus should be placed as close to the bed as possible, preferably in the bedroom itself. The technician who trains the patient in self-tonometry should instruct the patient how to instill eye drops while still lying down on his/her back. The fluorescein anesthetic drops should be placed at the bedside, and the patient will be instructed to respond to the alarm clock ring by moving promptly to the apparatus. The preliminary estimate is that a trained patient will be able to perform self-tonometry on both eyes within three minutes. At the scheduled time, and following the protocol of AGIS and OHTS, the patient will take two consecutive measurements, recording them in their notebook. If the values differ by 2 mm Hg or more, the patient will take a third measurement. The patient will then repeat the measurements on the opposite eye. Thus, in a given week, 42 IOP measurements will preferably be obtained for each eye.

Parallel with the period of self-measurement at home, depending on the patient's confidence with her/his measurement technique, but preferably at least weekly, each patient's self-tonometry performance can be reassessed at a return visit to the clinic and compared with IOP measurements obtained by an experienced measurer.

For each sampled hour, the home week self-tonometry mean IOP can be compared with to the clinic daytime IOP derived in the week prior to the one-week home self-tonometry period. The clinic template is useful to assess whether the home self-tonometry measurements are equivalent to clinic measurements. One can also assess if there is any "offset" (perhaps consistently lower or higher readings at home) that must be taken into account in continuing training of patients in self-tonometry. One can also investigate if the weekly measurements in the clinic in the month after the in-home study by the patient using self-tonometry are comparable to those values obtained by an expert measurer at the same time. Finally, overall multiple regression models can be developed in which the outcome is an IOP measurement for a patient and the predictors can include the

type of measurer, the type of setting, the patient age, the patient gender, and the patient race. Such models can help clarify which factors are predictive of the value of an IOP measurement, to see if there are differential effects among these factors and to test for interactions among factors.

FIG. 17 shows the results of an experiment wherein the self-tonometry apparatus of the present invention was used by patients to conduct 24-hour IOP self-measurement at home. After a single instructional session, each patient was easily able to obtain the correct applanation endpoint on his eye, making the two Landolt-like rings the same shape and then vernier aligning them. Each IOP point obtained at home was the mean of three consecutive readings for the eye. If a reading varied by more than 2.0 mm Hg, an additional reading was made.

Home self-tonometry data can also be recorded with an attachment to the self-tonometry apparatus of the present invention. Such an attachment could provide a direct, valid, verifiable, highly dependable assessment of the reliability of use of the apparatus at home by recording relevant data. Data recording during self-tonometry could include the 1) day, 2) time, 3) a still image of the final applanation pattern and, with a mechanical connection to the tonometer dial knob 4) the dial reading of IOP. No modification is necessary in the mechanism of the tonometer. The data can be stored on a standard digital video camera magnetic media that can be reviewed for quality and compliance during a patient's visit to the clinic. The recording could be activated by the patient's pressure on sensors in the chin-forehead rest.

In addition, an automated apparatus for acquisition of self-tonometry data is contemplated in order to provide the glaucoma population with the benefit of more IOP data and 24-hour IOP data on which their ophthalmologists can base their clinical decisions. Proximity devices can be used to detect the presence of the eye as the tonometer tip is applied to the cornea. Once the tip is in contact with the cornea, image recognition software can use stepper motors to move the tonometer through its 3-axes of movement (up and down, right and left, in and out) until the applanation pattern is centered. The knob on the outside of the tonometer can be

automatically adjusted until the measurement endpoint pattern is reached. At that point, date, time, image and IOP can be recorded.

In an alternative embodiment of the present invention depicted in FIGS. 18-20, the self-tonometry apparatus can be configured to be held by the patient with both hands, similar to binoculars. The hand-held apparatus is rested on the brow similar to the Perkins version of the Goldmann applanation tonometer, and includes a Goldmann tonometer tip illuminated by a blue LED. The hand-held apparatus incorporates a patient viewing component and an applanation mechanism.

With one viewing component (FIG. 18), during applanation of the test eye, the observing eye views the applanation pattern via a classical optical train: a beam splitter, a mirror and an image focusing element. With an alternative viewing component (FIG. 19), during applanation of the test eye, the observing eye views the video image of the applanation pattern via the output of an ultra-miniature CCD color camera (for example, 1.3 oz, 25 x 25 mm, Defender Security or equivalent) fed to a miniature color LCD monitor (for example, 18 mm diagonal, 800 x 600 pixel, CRL Opto Limited or equivalent).

In the applanation mechanism (FIG. 20), a rotary voice coil (for example, 1.8 in wide x 1.2 in long, Rotary Voice Coil, BEI Technologies, Inc. or equivalent) applies a controlled applanating load to the cornea through a Goldmann applanation tonometer tip, where the current coil and magnetic core provide movement about a pivot. With current in the coil, the magnetic core advances the tonometer tip. A strain gauge senses the applanating load applied to the cornea, and a microprocessor controls this load and provides signal conditioning to give the IOP reading. The tonometer tip is poised by counterbalancing mass around the pivot, thus neutralizing the effect of gravity in measurements made sitting and lying. A coiled spring maintains the at rest position of the tonometer tip. The applanating load is preferably limited to the applanation standard 8 grams by microprocessor control of maximum current to the current coil.

As alternatives to the rotary voice coil described above, other force application devices could include a linear voice coil, bimetallic elements, NITINOL memory alloys, parallel differential motion of near members (to amplify movement), thermal-activated bellows, and bimorphic elements, among others.

For self-measurement of IOP for each patient, a technician adjusts the apparatus inter-pupillary distance, and like measuring lens vertex distance, the tonometer tip-to-cornea distance. The patient holds the apparatus to her/his face, centers the tonometer tip before the eye to be applanated, and then activates the microprocessor with a finger-tip button. The tip of the tonometer advances until it contacts the cornea with an initial applanating load, preferably 1 gram (10 mm Hg). The patient centers the applanation pattern with fine adjustments of the apparatus position, and then controls the applanating load with a slide, lever, rocker, or the like to reach the endpoint applanation pattern. The IOP reading is preferably shown on a LCD readout.

For an external monitoring option, video output (in FIG. 18 from an added ultra-miniature CCD color camera, and in FIG. 19 from its ultra-miniature CCD color camera) is fed to a monitor for teaching patients how to use the apparatus. For an external recording option, digital camera media records the applanation images and the IOP readings (video output and microprocessor output, respectively) for subsequent assessment of the endpoint patterns patients obtain at home.

While embodiments of the invention have been illustrated and described, it is not intended that these embodiments illustrate and describe all possible forms of the invention. Rather, the words used in the specification are words of description rather than limitation, and it is understood that various changes may be made without departing from the spirit and scope of the invention.

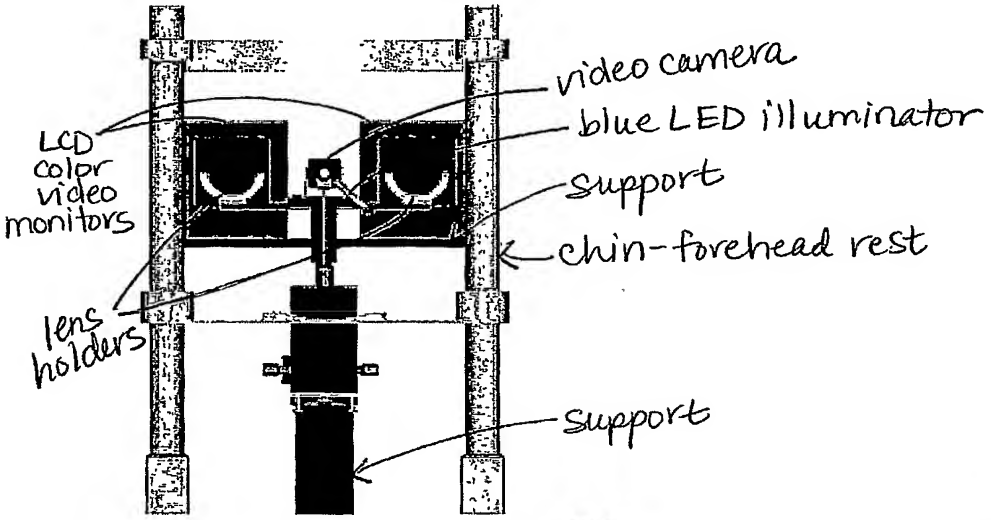

FIG. 1

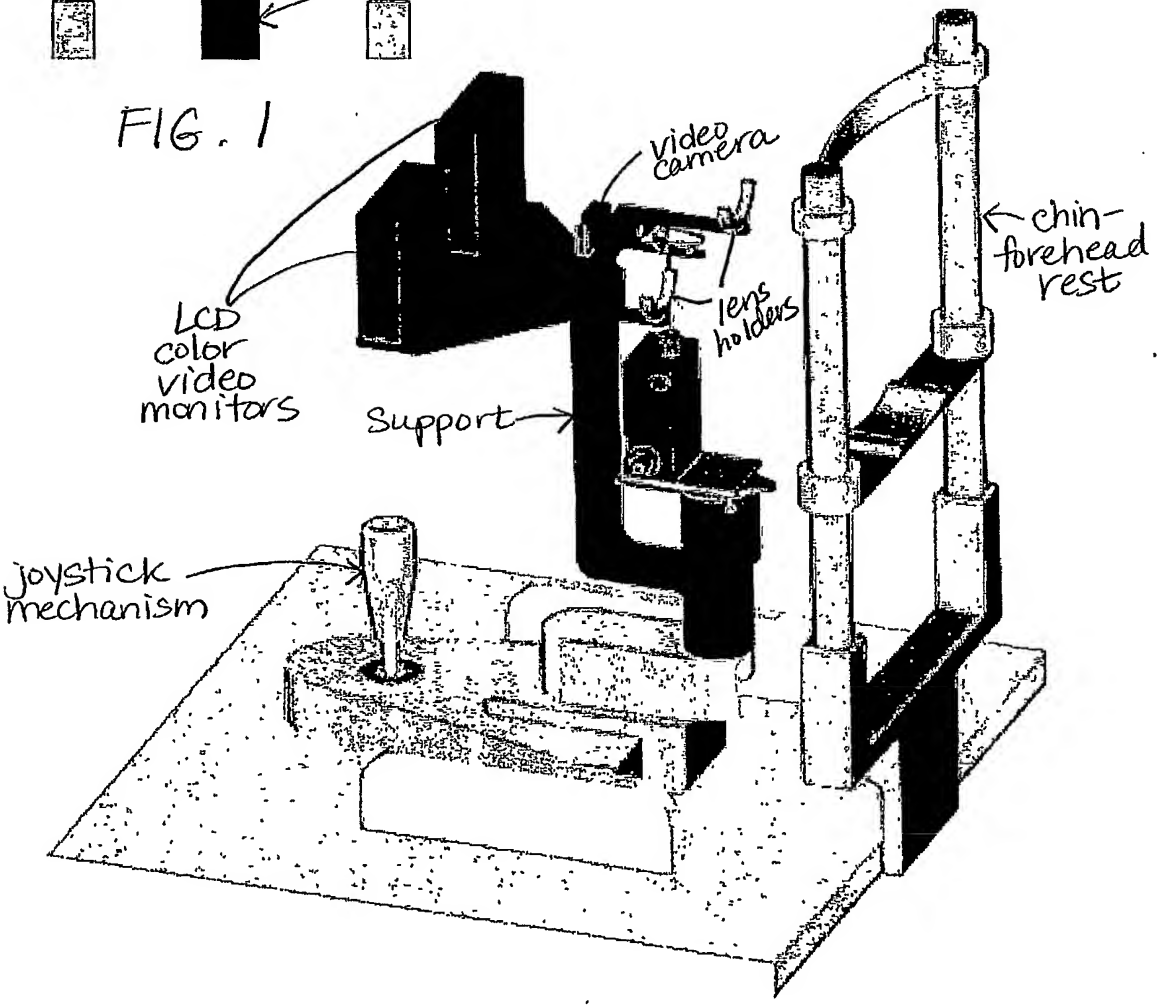

FIG. 2

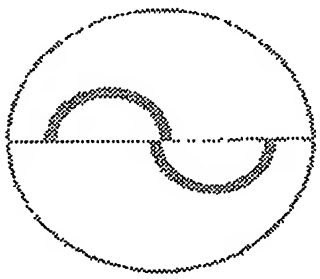

FIG. 3

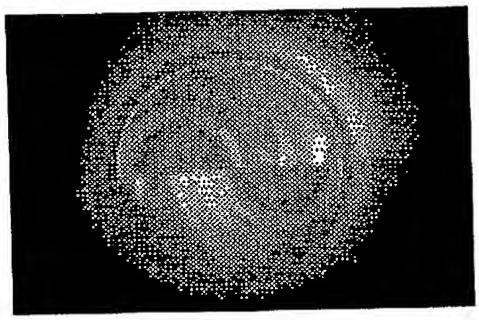

FIG. 4

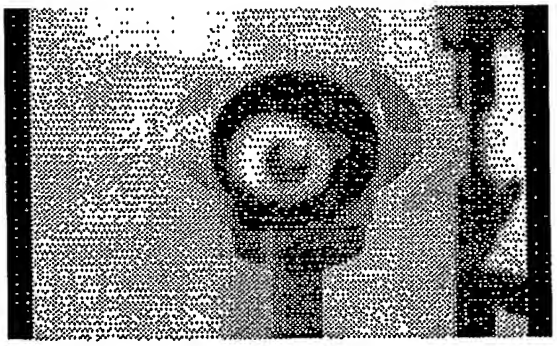

FIG. 5

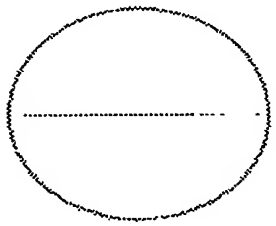

FIG. 6

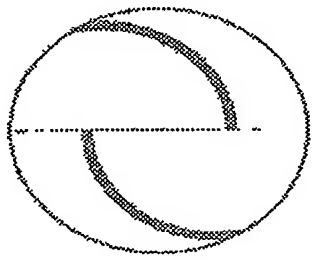

FIG. 7

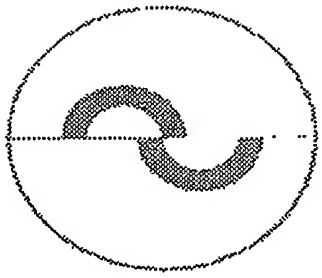

FIG. 8

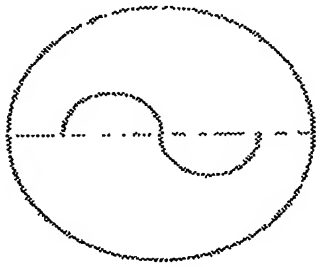

FIG. 9

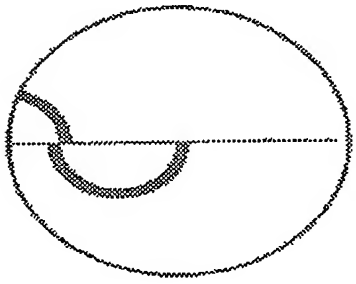

FIG. 10

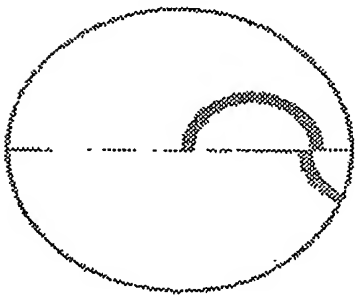

FIG. 11

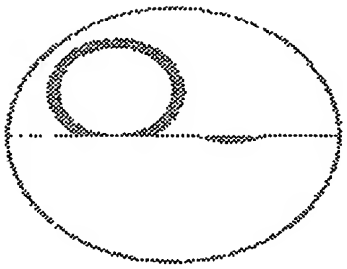

FIG. 12

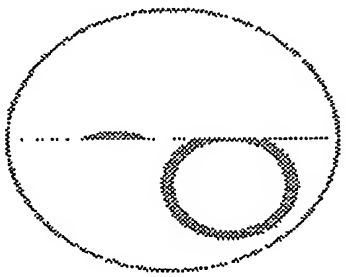

FIG. 13

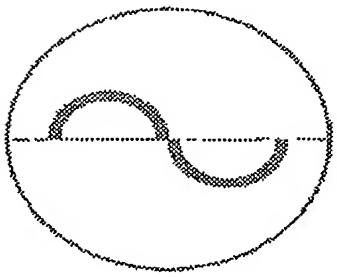

FIG. 14

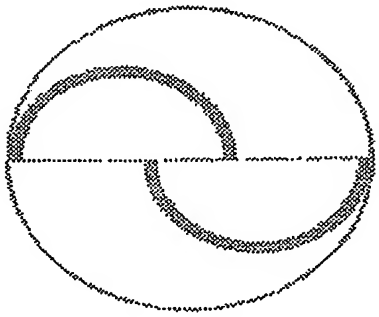

FIG. 15

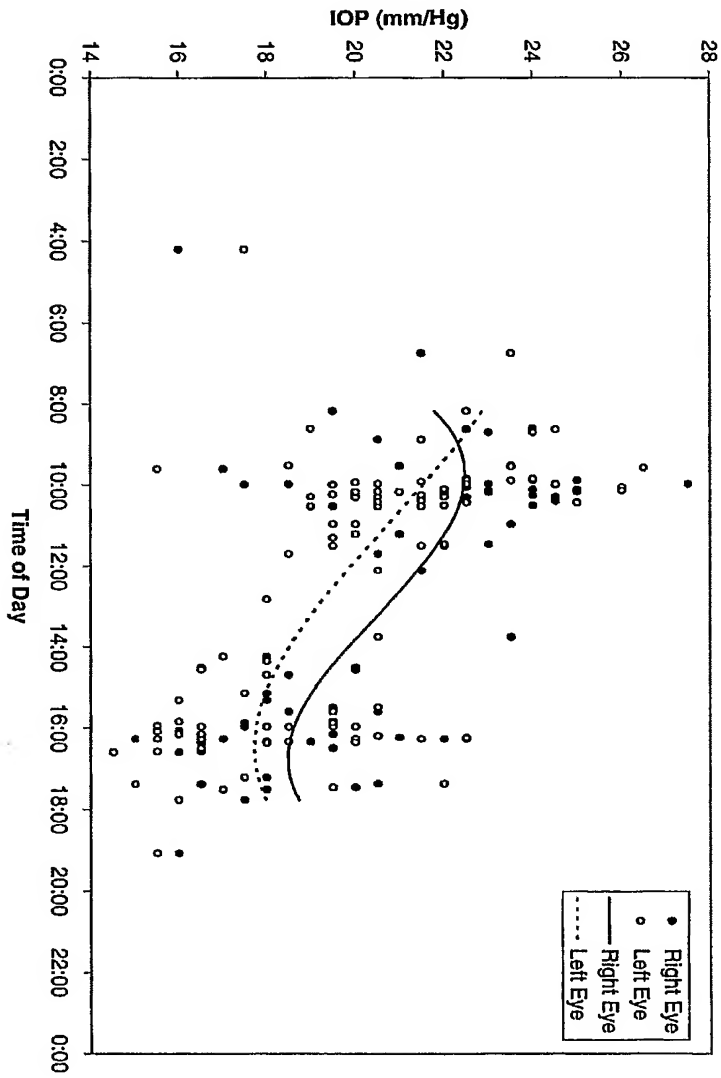

FIG. 16

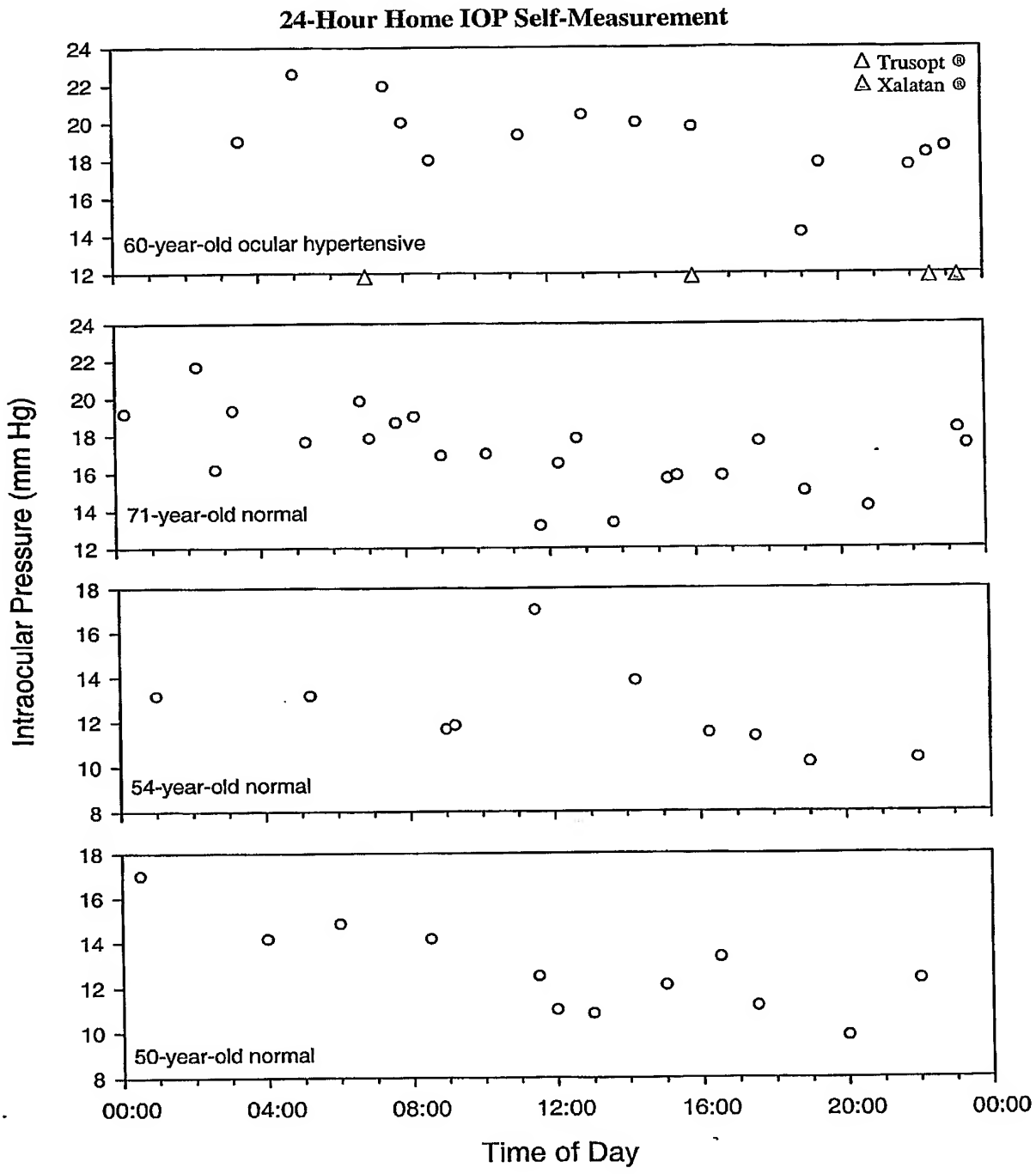

FIG. 17

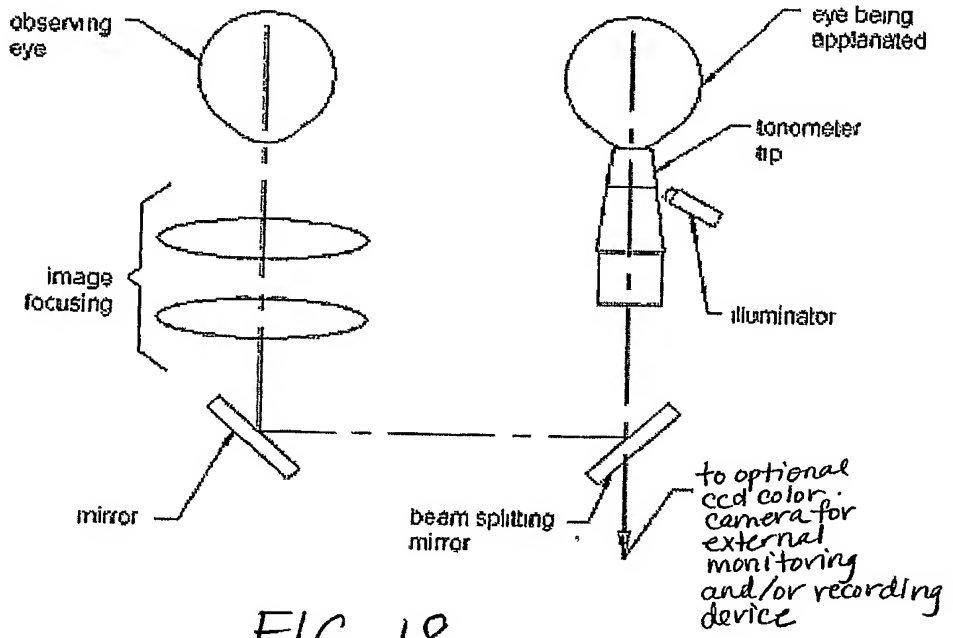

FIG. 18

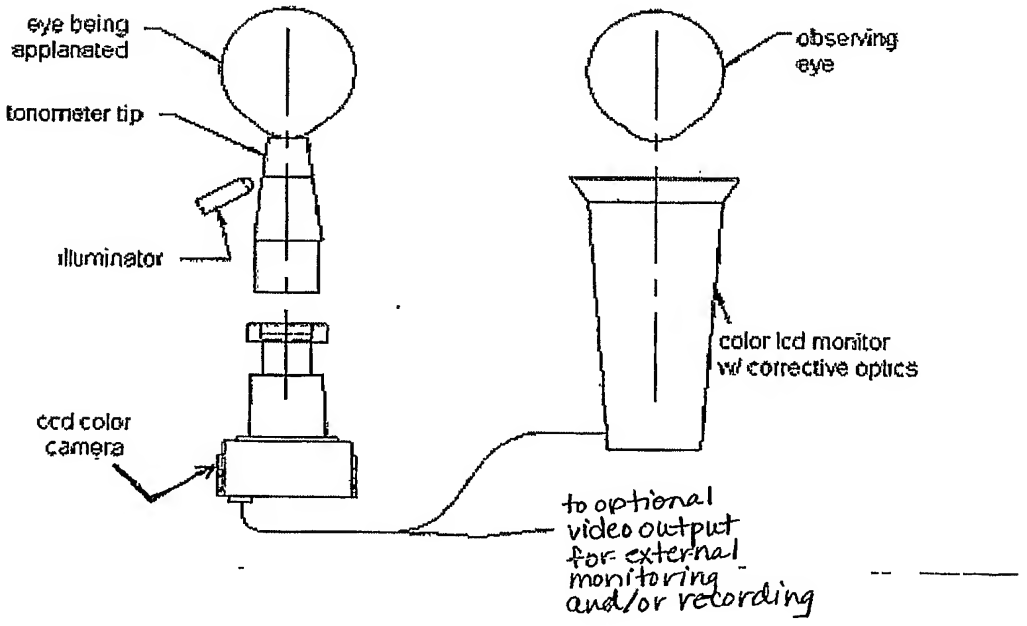

FIG. 19

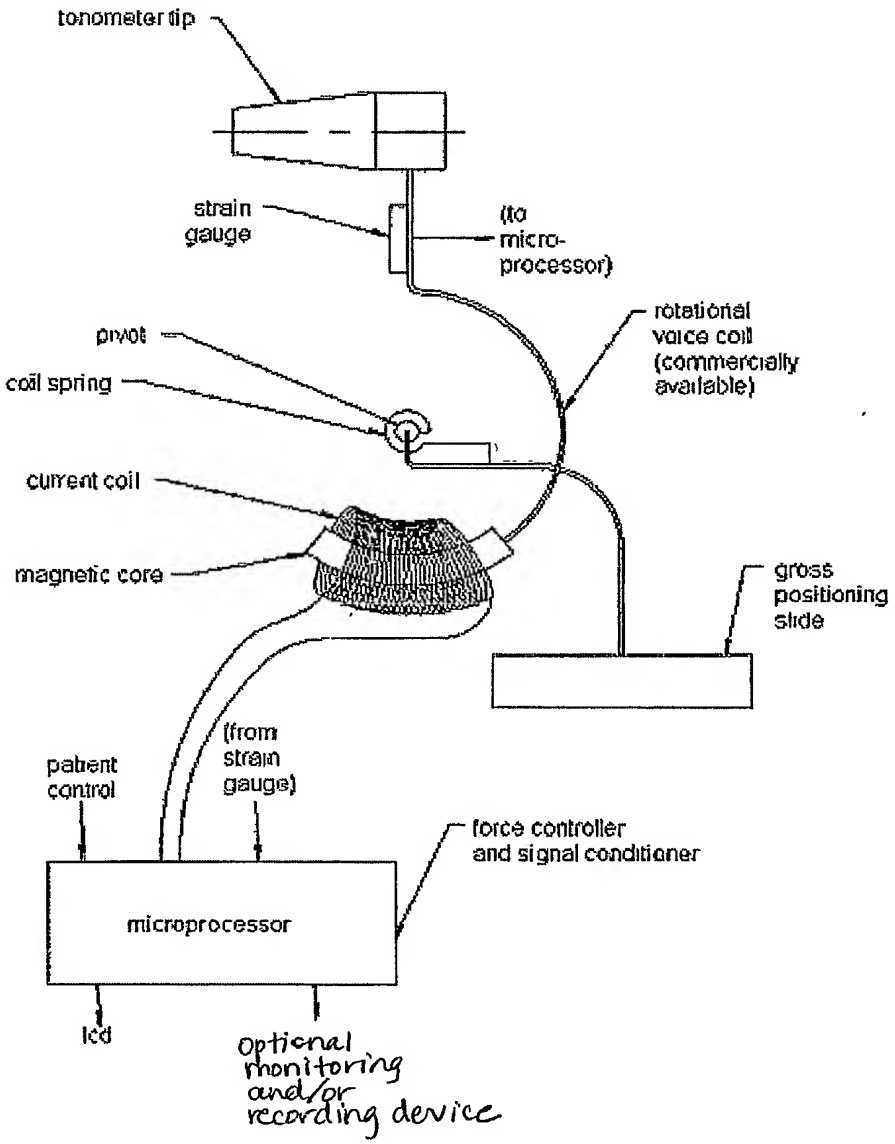

FIG. 20